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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/932,474

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Timothy E. Benson

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10/01/2004

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,474

Applicant(s)

BENSON ET AL.

Examiner

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 7-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 51-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/25/02; 3/11/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 1-57 are pending in the application.

Election/Restriction

- [2] Applicants' election without traverse of Group I, claims 1-6 and 51-57, filed July 28, 2004, is acknowledged.

- [3] Claims 7-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 28, 2004.

Priority

- [4] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application numbers 60/226,239 and 60/226,269, both filed August 17, 2000, is acknowledged.

Information Disclosure Statement

- [5] All references cited in the information disclosure statements (IDS) filed March 25, 2002 have been considered by the examiner. All references with the exception of "Database Accession No." references cited in the IDS filed March 11, 2003 have been considered by the examiner. "Database Accession No." references have not been

considered as there is no citation of the relevant database and there is no date of publication. A copy of each IDS is attached to the instant Office action.

Specification/Informalities

[6] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification, e.g., page 31, line 12 and all other hyperlinks embedded in the specification, is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[7] The specification is objected to as referring to "Table 1" (e.g., page 4, line 9), however, there does not appear to be a Table 1 in the specification. Applicants are requested to correct this discrepancy.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[8] Claim(s) 1-6 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 1, 2 (claim 3 dependent therefrom), 4 (claim 5 dependent therefrom), and 6 are indefinite in the recitation of “amino acids listed in Table...” Without a reference amino acid sequence, e.g., SEQ ID NO:1, it is unclear as to the relative positions of amino acids listed in the recited Table in the molecule or molecular complex. It is suggested that applicants clarify the meaning of the claims.

[b] Claim 6 is indefinite in the recitation of “structurally homologous to an *S. aureus* FemA molecule or molecular complex” as it is unclear as to whether the recited “structure” is intended to be interpreted as the primary amino acid sequence or the three-dimensional structure. Further, it is unclear as to how “homologous” a molecule or molecular complex must be to be included within the scope of the claim. Also, it is unclear as to the proteins that are considered to be *S. aureus* FemA molecules or molecular complexes such that a skilled artisan can determine whether the claimed molecule or molecular complex is sufficiently “structurally homologous” to be included within the scope of the claim. It is suggested that applicants clarify the meaning of the term.

[c] Claim 6 is indefinite in the recitation of “represented by” as it is unclear as to the intended meaning of the term in the context of a molecule or molecular complex. It is suggested that applicants clarify the meaning of the term.

[d] Claim 51-55 are indefinite in the recitation of “*S. aureus* FemA” as it is unclear as to the scope of proteins that are meant to be encompassed by the terms. It is suggested that applicants clarify the meaning of the claims by providing distinguishing characteristics of an “*S. aureus* FemA” protein such that a skilled artisan can distinguish

Art Unit: 1652

those proteins that are intended to be encompassed within the scope of the claims from those that are not. For example, by identifying the "*S. aureus* FemA" by a sequence identifier.

[e] Claim 56 is unclear in the recitation of "including amino acids having the sequence of SEQ ID NO:1." It is unclear from the claim and the specification as to whether the phrase is meant to be interpreted as meaning the crystallized *S. aureus* FemA polypeptide has the sequence of SEQ ID NO:1, or if the crystal comprises an *S. aureus* FemA polypeptide and further includes "amino acids having the sequence SEQ ID NO:1." In the interest of advancing prosecution, the phrase has been interpreted as meaning the crystallized *S. aureus* FemA polypeptide has the sequence of SEQ ID NO:1. It is suggested that applicants clarify the meaning of the claim.

[f] Claims 56 and 57 are confusing in that the claims are drawn to a crystal of an *S. aureus* FemA polypeptide of SEQ ID NO:1 or a selenomethionine variant of SEQ ID NO:1. However, the prior art (Tschierske et al. *FEMS Microbiol Lett* 171:97-102; cited in the IDS filed March 25, 2002) teaches that a polypeptide that is 100% identical to SEQ ID NO:1, referred to as "FmhC," has only 37% amino acid sequence identity to *S. aureus* FemA (page 99, Table I). Thus, it is unclear as to how the polypeptide of SEQ ID NO:1 is considered to be an *S. aureus* FemA. Applicants are requested to clarify this discrepancy.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[9] Claim(s) 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim(s) are drawn to a molecule or molecular complex. The claim(s) read on a product of nature and should be amended to indicate the hand of the inventor, e.g., by insertion of "purified" or "isolated". See MPEP § 2105.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[10] Claim(s) 1-6 and 51-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-6 are drawn to a genus of molecules or molecular complexes comprising at least a portion of an *S. aureus* FemA or FemA-like substrate binding surface or a genus of molecules or molecular complexes that are homologous thereto. Claim 51 is drawn to a method for crystallizing a genus of *S. aureus* FemA molecules or molecular complexes. Claims 52-57 are drawn to a genus of *S. aureus* FemA crystals.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of molecules or molecular complexes comprising at least a portion of an *S. aureus* FemA or FemA-like substrate binding surface or a genus of molecules or molecular complexes that are homologous thereto, i.e., the *S. aureus* FemA of SEQ ID NO:1 and the specification discloses only a single representative species of *S. aureus* FemA crystals, i.e., a crystal of the purified *S. aureus* FemA of SEQ ID NO:1 having an orthorhombic space group symmetry of $P2_12_12_1$ and the unit cell dimensions of $a=53.9\text{\AA}$, $b=90.4\text{\AA}$, and $c=109.3\text{\AA}$ and $\alpha=\beta=\gamma=90^\circ$ (see particularly p. 15 of the specification). The specification fails to describe any additional representative species of the recited genus of molecules or molecular complexes comprising at least a portion of an *S. aureus* FemA or FemA-like substrate binding

surface or *S. aureus* FemA crystals as encompassed by the claims. In this case, the single representative species fails to describe each genus of molecules or molecular complexes or crystals, which encompasses *widely* variant species with respect to the structures and functions of the molecules or molecular complexes and the *S. aureus* FemA protein sequences and crystal structures of the *S. aureus* FemA crystals. Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[11] Claims 1-6 and 51-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *S. aureus* FemA polypeptide of SEQ ID NO:1; a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 by preparing purified *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 4% PEG 8000, 100 mM Tris buffer, pH 8.5 at 4 degrees Celsius, a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 having methionine replaced with selenomethionine by preparing purified selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 30% PEG 4000, 100 mM Tris buffer, pH 8.5, 200 mM $MgCl_2$ at 20 degrees Celsius, and a crystal of the purified *S. aureus* FemA of SEQ ID NO:1 having an orthorhombic space group symmetry of $P2_12_12_1$ and the unit

Art Unit: 1652

cell dimensions of $a=53.9\text{\AA}$, $b=90.4\text{\AA}$, and $c=109.3\text{\AA}$ and $\alpha=\beta=\gamma=90^\circ$, does not reasonably provide enablement for all molecules or molecular complexes as encompassed by claims 1-6, methods for crystallizing any *S. aureus* FemA polypeptide under the broad range of conditions as recited in claim 51, or all crystals of an *S. aureus* FemA polypeptide as encompassed by claims 52-57. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: Claims 1-6 are so broad as to encompass all molecules or molecular complexes comprising at least a portion of an *S. aureus* FemA substrate binding surface or site as encompassed by claims 1-5 or structural homologs thereof as encompassed by claim 6. As claims 1-6 have been given their

Art Unit: 1652

broadest reasonable interpretation in accordance with MPEP 2111, the claimed molecules and molecular complexes encompass essentially any protein. Claim 51 is so broad as to encompass a method for crystallizing any *S. aureus* FemA polypeptide, including all mutants and variants of the polypeptide of SEQ ID NO:1. Further, it is noted that the claim recites an extremely broad set of crystallization conditions. Claims 52-56 are so broad as to encompass a vast number of *S. aureus* FemA crystals, having any space group symmetry and/or unit cell dimensions, including all mutants and variants of the polypeptide of SEQ ID NO:1. In this case the disclosure is limited to the *S. aureus* FemA polypeptide of SEQ ID NO:1; a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 by preparing purified *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 4% PEG 8000, 100 mM Tris buffer, pH 8.5 at 4 degrees Celsius, a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 having methionine replaced with selenomethionine by preparing purified selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 30% PEG 4000, 100 mM Tris buffer, pH 8.5, 200 mM MgCl₂ at 20 degrees Celsius, and a crystal of the purified *S. aureus* FemA of SEQ ID NO:1 having an orthorhombic space group symmetry of P2₁2₁2₁ and the unit cell dimensions of a=53.9Å, b=90.4Å, and c=109.3Å and $\alpha=\beta=\gamma=90^\circ$.

Art Unit: 1652

- The lack of guidance and working examples: The specification provides only a single working example of the claimed molecule or molecular complex, *i.e.*, the *S. aureus* FemA polypeptide of SEQ ID NO:1. The specification provides only two working examples of the claimed method of crystallization, *i.e.*, a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 by preparing purified *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 4% PEG 8000, 100 mM Tris buffer, pH 8.5 at 4 degrees Celsius, a method of crystallizing the *S. aureus* FemA polypeptide of SEQ ID NO:1 having methionine replaced with selenomethionine by preparing purified selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 to a final concentration of 12 mg/mL and crystallizing selenomethionine *S. aureus* FemA polypeptide of SEQ ID NO:1 by hanging drop method in a solution of 30% PEG 4000, 100 mM Tris buffer, pH 8.5, 200 mM $MgCl_2$ at 20 degrees Celsius. The specification provides only a single working example of the claimed crystal, *i.e.*, a crystal of the purified *S. aureus* FemA of SEQ ID NO:1 having an orthorhombic space group symmetry of $P2_12_12_1$ and the unit cell dimensions of $a=53.9\text{\AA}$, $b=90.4\text{\AA}$, and $c=109.3\text{\AA}$ and $\alpha=\beta=\gamma=90^\circ$. These working examples fail to provide the necessary guidance for making the entire scope of crystal compositions broadly encompassed by the claims. Regarding claims 1-6, the specification fails to provide guidance regarding those amino acids of SEQ ID NO:1 that may be altered by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired FemA activity.

Art Unit: 1652

Furthermore, the specification fails to provide guidance as to how to use those variant polypeptides having activities other than the desired FemA activity, e.g., non-functional polypeptides or polypeptides having activity other than FemA activity. Regarding claims 51-57, the specification fails to provide guidance regarding crystallization of other *S. aureus* FemA proteins using other methods/conditions of crystallization with an expectation of obtaining diffraction quality crystals.

- The high degree of unpredictability in the art is supported by the state of the art: Regarding claims 1-6, the amino acid sequence of a protein determines its structural and functional properties. Predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired FemA activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within a protein's sequence where modifications can be made with a reasonable expectation of success in obtaining a polypeptide having the desired FemA activity/utility are limited and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g., multiple substitutions.

The state of the art provides evidence for the high degree of unpredictability in altering a protein's sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein

Art Unit: 1652

Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). The teachings of Branden et al. are exemplified by Witkowski et al. (*Biochemistry* 38:11643-11650), who teach that a single amino acid substitution results in conversion of the parent polypeptide's activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see e.g., Table 1, page 11647). Thus, the prior art acknowledges the unpredictability of altering a protein sequence with an expectation of obtaining a protein having a desired function and discloses that even a single substitution in a polypeptide's amino acid sequence may completely alter the function of a polypeptide.

Regarding claims 51-57, Branden et al. ("Introduction to Protein Structure Second Edition", Garland Publishing Inc., New York, 1999) teach that protein crystallization is usually quite difficult to achieve and the formation of protein crystals is critically dependent on a number of different parameters, including pH, temperature, protein concentration, the nature of the solvent and precipitant, as well as the presence of added ions and ligands to the protein (page 375, middle). Branden et al. teach that even small changes in the crystallization parameters, e.g., pH, can cause the molecules to pack in different ways to produce different crystal forms (page 375, bottom). Thus, even minor modifications to a crystallization method may result in crystals that are

Art Unit: 1652

distinct in structure having different space group symmetry and unit cell dimensions. At least in view of the teachings of Branden et al. a skilled artisan would recognize the high degree of unpredictability in generating the broad scope of claimed crystals.

This unpredictability is evidenced by the teachings of the specification, which describes the difficulties of protein concentration/solubilization (pp. 47-48) and the difficulty of obtaining diffraction-quality crystals of *S. aureus* FemA of SEQ ID NO:1 at 20 degrees Celsius.

- The amount of experimentation required is undue: Regarding claims 1-6, while methods of generating variants of a given protein are known in the art, *e.g.*, site-directed mutagenesis, it is not routine in the art to screen for *all* proteins having a substantial number of substitutions or modifications and having *any* function, as encompassed by the instant claims. Regarding claims 51-57, while methods of protein crystallization are known, it is *not* routine in the art to screen a vast number proteins under any crystallization conditions or to experiment to make all crystals as broadly encompassed by the claims.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high degree of unpredictability as evidenced by the prior art, and the amount of experimentation required to make and use all molecules or molecular complexes, make all methods, or make all crystals as broadly encompassed by the claims, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[12] Claim(s) 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tschierske et al. (*FEMS Microbiol Lett* 171:97-102; cited in the IDS filed March 25, 2002) as evidenced by GenBank Accession Number AF106851.

The claims are drawn to a molecule or molecular complex comprising at least a portion of an *S. aureus* FemA or FemA-like substrate binding surface or site or a molecule or molecular complex homologous thereto.

Art Unit: 1652

Tschierske et al. teaches an *S. aureus* polypeptide referred to as "FmhC" and teach the sequence of FmhC has GenBank Accession Number AF106851 (page 99, bottom). GenBank Accession Number AF106851 teaches a polypeptide that is 100% identical to SEQ ID NO:1 of the instant application (see Appendices A and B). This anticipates claims 1-6 as written.

Citation of Relevant Art

[13] The following reference is made of record as the reference is considered to be pertinent to applicant's disclosure: Benson et al. *Structure* 10:1107-1115. The reference is not relied upon for a prior art rejection as the reference was published after the effective filing date of the instant application.

Conclusion

[14] Status of the claims:

- Claims 1-57 are pending.
- Claims 7-50 are withdrawn from further consideration.
- Claims 1-6 and 51-57 are rejected.
- No claim is in condition for allowance.
- Claims 51-57 would appear to be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's

Art Unit: 1652

supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.



David J. Steadman, Ph.D.

Primary Examiner

Art Unit 1652

09-28-04